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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,580	12/09/1999	MILES B. BRENNAN	3718-3	9015

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/08/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,580

Applicant(s)

BRENNAN ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-7,9,10,13,16,18-21,23-29,31-39,53-57,59,66-68,70,73,75,80-82,85-91,93-95,98-100,102,103 and 108-118.

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DETAILED ACTION

Application status

1. Receipt of applicant's amendment and election of sequence 8a file July 1, 2002 is acknowledged. In a telephone interview with Shannon Mrksich on September 30, 2002 it was further explained that claims 108-114 were separated from originally elected Group I into another invention group because the claims are drawn to a method distinct from that of claims 1 *et seq.* in that claim 1 is a method for decreasing body weight employing an MSH agonist whereas claim 108 is drawn to a method for increasing body weight and employs an MSH antagonist. Additionally, the elected compound, that of claim 8a (now 115a) is that of an α -MSH analog whereas the compounds of claim 112 clearly are not α -MSH analogs nor does claim 108 recite an α -MSH analog compound. Thus applicant elected the group comprising claims 1 *et seq.* in the originally elected Group I but excluding claims 108-114 and it was agreed that examination would be restricted to the method of claim 1 and claims dependent therefrom and related thereto wherein the compound is an α -MSH, an α -MSH analog or an α -MSH agonist which also excludes mimetics. **The claims presently under prosecution are: claims 1, 4 (in part), 5 (in part), 7, 9, 10, 13, 16, 18-21, 23-29, 31-39, 53-56, 59, 98, 99, 102, 103 and 115.**

2. For the record, the first Office action, paper no. 8 mailed April 16, 2001, is withdrawn in its entirety in view of the requirement for restriction and new grounds for rejection.

Informalities

3. The disclosure is objected to because of the following informalities:

(a) Claim 115 is objected to because it includes letters followed by periods which identify claim elements. Such letter identifiers in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or letters which may appear in the claims. See MPEP § 608.01(m).

(b) In claim 115 at b. the semicolons after "amino acid", "Lys", "ornithine" and 1, 2-diaminobutyric acid should be commas.

Appropriate correction is required.

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Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4 (in part), 5 (in part), 7, 9, 10, 13, 16, 18-21, 23-29, 31-39, 53-56, 59, 98, 99, 102, 103 and 115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 1 fails to provide antecedent basis for elected claim 115 (8) compounds which are α -MSH analogs. It is suggested to amend claim 1 at line 4 (marked-up version) to recite -- α -MSH, α -MSH analog and an α -MSH agonist--.

(b) Claim 1 lacks antecedent basis for "said compound is administered" at line 5 (marked-up version) because the "therapeutic composition" is administered. It is suggested to rewrite the former, for example, as --said therapeutic composition is administered to the periphery of said animal and the amount of the compound in said therapeutic composition is effective to measurably..."--.

(c) Claim 4 is confusing in reciting nonelected subject matter. It is suggested to delete "a peptide mimetic...agonist activity" at lines 3-5 in the marked-up version of the claim.

(d) Claim 4 lacks antecedent basis in amended claim 1 for "MSH". It is suggested to amend claim 4 to change "MSH" at all occurrences to -- α -MSH--.

(e) Claim 5 is confusing in reciting non-elected subject matter. It is suggested to delete " β -MSH and γ -MSH".

(f) Claim 115 is confusing in the line 1 recitation, "is an a MSH analog". The "a" should be changed to -- α -- as recited in original claim 8.

(g) Claim 115 appears to lack antecedent basis in claim 1 for the recitation in the last two lines wherein "the cyclized portion of the compound is conformationally restricted in a manner which is compatible with the reactivity of the compound with receptors of the central nervous system" (CNS) because this implies interaction of the compound with receptors in the CNS whereas claim 1 recites the limitation that "administration of said

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compound minimizes delivery of said compound to the [CNS]". Clarification of the relationship between the two recitations in the two claims is required.

(h) Claim 9 and all other claims dependent from claim 1 which recite "MSH" lack antecedent basis for "MSH" in amended claim 1. It is suggested to amend the claims to change "MSH" at all occurrences to -- α -MSH--

(l) Claims 1, 4, 5, 115 and all other claims reciting " α -MSH" (after amendment) are indefinite because the antecedent " α -MSH" is unclear, i.e., on which " α -MSH" are the claimed analogs based? The specification identifies several POMC nucleic acid sequences in the public domain as well as the sequence of the human α -MSH, SEQ ID NO:2 (page 38). The " α -MSH" recited in the claims must be identified either by SEQ ID NO: or by the modifier, "human", which points to the sequence at page 38

Prior art of interest

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art contains numerous disclosures of melanocortin receptor agonist and antagonists of which a few refer to involvement of these receptors and the ligand, α -MSH, in obesity and in extreme weight loss conditions such as anorexia as well as melanocortin receptor binding compounds and screening methods for discovery of such compounds. However, none of the references of record alone or combined disclose or suggest the claimed invention method of decreasing body weight by administering an α -MSH or α -MSH agonist wherein administration is to the periphery of the recipient and minimizes delivery to the central nervous system. Two recent publications, WO 00/35952 and 6,376,509, disclose MSH agonists and suggest their use for treating eating disorders. However, neither of these references, in addition to being published after applicant's effective, discloses or suggests the claimed invention treatment method.

Conclusion

6. The claims are free of the prior art and may be placed in condition for allowance by resolution of the informal issues and the rejections under 112, second paragraph set forth above.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-

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3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.



Stephanie Zitomer, Ph.D.

October 1, 2002

**STEPHANIE W. ZITOMER
PRIMARY EXAMINER**